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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,451	09/09/2003	Maria Villani	14431-16	4939
45200	7590	06/02/2006	EXAMINER	
PRESTON GATES & ELLIS LLP 1900 MAIN STREET, SUITE 600 IRVINE, CA 92614-7319			VANIK, DAVID L	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 06/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/659,451

Applicant(s)

VILLANI, MARIA

Examiner

David L. Vanik

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,6,7 and 10-26 is/are pending in the application.
- 4a) Of the above claim(s) 10-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,6,7 and 23-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of the Applicant's Remarks and Amended Claims filed on 4/6/2006.

The 35 USC §102 rejections over RU 2176511 C1 ('511) are hereby **maintained**. However, as a result of Applicant's amendments, the 35 USC §101 rejections are hereby **withdrawn**. Because claim 9 has been cancelled, the 35 USC §103 rejection over RU 2176511 C1 ('511) in view of US patent 3,896,238 ('238) is hereby **withdrawn**.

MAINTAINED REJECTIONS:

The following is a list of maintained rejections:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 3-4, 7, and 24-25 are rejected under 35 U.S.C. 102(a) as being anticipated by RU 2176511 C1 ('511).

'511 disclose a dermatological composition comprising a Porifera-derived material, a fresh-water sponge of the *Spongillidae* family, and ethyl alcohol, a pharmaceutically acceptable excipient (abstract). As the fresh-water sponge-based composition is a water-ethanol extract, the composition comprises both ethanol and water. Additionally, the fresh-water sponge-based composition may be included in lotions, gels, creams, and cosmetic masks (page 4). It should be noted that claims 1 and 7 are product-by-process claims. As such, claims 1 and 7 will be treated as product claims and not as method claims. By disclosing a composition comprising a Porifera-derived product, a fresh-water sponge of the *Spongillidae* family, the composition advanced by '511 et al anticipates the instant claims 1 and 7 (abstract).

The claims are therefore anticipated by 2176511 C1 ('511).

Response to Arguments

Applicant's arguments filed on 4/6/2006 have been fully considered but they are not persuasive. In response to the 12/6/2005 Non-Final Rejection, Applicant has amended the instant claim set to recite the limitation "wherein said therapeutic composition is not an extract of said substantially pure powdered *Spongilla* sp." With respect to this, it is Applicant's assertion that the instant amendment overcomes the '511 rejection and places the instant claim set in condition for allowance. The examiner respectfully disagrees with this assertion.

Giving the instant claim 1 its broadest reasonable interpretation, the examiner respectfully submits that the limitation “wherein said therapeutic composition is not an extract of said substantially pure powdered *Spongilla* sp.” reads as a product-by-process limitation. That is, the examiner respectfully submits that the limitations of the instant claim 1 are (1) substantially pure powdered *Spongilla* sp. and (2) at least one pharmaceutically acceptable excipient. The phrases “not an extract” and “made in accordance with Good Manufacturing Practices” are deemed to recite process steps. Since the examiner respectfully submits that neither of the above phrases breath meaning or add breadth to the instant claim set, the process limitations are granted little patentable weight. As such, the examiner respectfully submits that claims 1, 3-4, 7, and 24-25 remain rejected over ‘511.

NEW REJECTIONS:

The following is a list of new rejections:

Claim Objections

Claims 4, 6-7, 24-25 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot be dependent on a cancelled claim. In the instant case, claim 2 has been cancelled and claims 4, 6-7, 24-25 remain dependent on the cancelled claim 2. See MPEP § 608.01(n). In order to expedite prosecution and

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examine the above improper claims, the examiner is interpreting the "claim 2" element of the instant claim 4 as being "claim 1." Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-4, 6-7, 23-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. As amended, the instant claim set recites the limitation "wherein said therapeutic composition is not an extract of said substantially pure powdered *Spongilla* sp." After carefully examining the instant disclosure, the examiner respectfully submits that support for this amendment is lacking and the addition of said limitation is new matter. Specifically, the limitation "not an extract" is not set forth in the instant specification. The specification, including paragraphs 0062 – 0068, have been carefully reviewed and sufficient support for the limitation "not an extract" was not found. Additionally, the limitation "*Spongilla* sp." was not found in the instant disclosure. Although the examiner acknowledges the limitation

“powdered Spongilla” is set forth in the instant disclosure (See paragraph 0040, for example), the limitation “Spongilla sp” was not found.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 23 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. As amended the instant claim 23 recites the limitation “at least 0.1%”. After carefully examining the instant disclosure, the examiner respectfully submits that support for this amendment is lacking and the addition of said limitation is new matter. Specifically, the limitation “at least 0.1%” is not set forth in the instant specification. Although the examiner acknowledges the limitation “approximately 0.1% to 100%” is set forth in the instant disclosure (See paragraph 0042, for example), the limitation “at least 0.1%” was not found. The examiner respectfully submits that “at least” is not tantamount to “approximately.”

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David L. Vanik whose telephone number is (571) 272-3104. The examiner can normally be reached on Monday-Friday 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

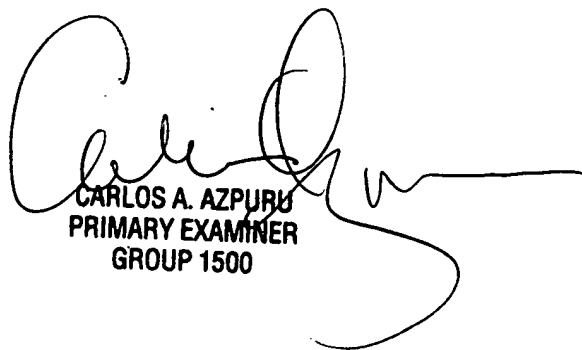
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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Vanik, Ph.D.
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5/30/06



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